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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,818	08/05/2003	John Joseph Harrington	0221-0003MCON	1411
27805	7590	02/10/2009		
THOMPSON HINE L.L.P. Intellectual Property Group P.O. BOX 8801 DAYTON, OH 45401-8801			EXAMINER CHEN, SHIN LIN	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 02/10/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/635,818	<b>Applicant(s)</b> HARRINGTON ET AL.	
	<b>Examiner</b> Shin-Lin Chen	<b>Art Unit</b> 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 7-28-08 & 11-5-08.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2-27 is/are pending in the application.
- 4a) Of the above claim(s) 12-21 and 23-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-11, 22, 26 and 27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicants' amendment filed 7-28-08 and 11-5-08 have been entered. Claims 2, 3, 22, 26 and 27 have been amended. Claims 2-27 are pending. Claims 2-11, 22, 26 and 27 are under consideration.

#### ***Specification***

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because there is no sequence identifier for the nucleotide sequence in Figures 29-35 and 37 or in the "BRIEF DESCRIPTION OF THE DRAWINGS". Each nucleotide sequence is required to have a sequence identifier. Appropriate correction is required.

#### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 2-11 and 22 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 7-9, 11 and 12 of U.S. Patent No. 7,033,782 ('782). Although the conflicting claims are not identical, they are not patentably distinct from each other because although drawn to different scope, they encompass the same invention and obvious variants thereof and are repeated for the reasons set forth in the preceding Official action mailed 1-29-08. Applicant's arguments filed 11-5-08 have been fully considered but they are not persuasive.

Applicants argue that the patents and application are either divisionals or continuations of divisionals from the original parent application 09/276,820, which has a restriction requirement. The '782 patent is directed to vectors that do not necessarily contain two promoters (amendment, p. 12-13). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 1-29-08. Applicants just provide a general statement that the patents and applications are divisionals and continuations but fail to point out which patent or application corresponds to which group in the original restriction requirement of 09/276,820. It is unclear which group in the original restriction requirement of 09/276,820 corresponds to the claims of '782 patent. Further, although '782 patent does not specifically mention a selectable marker, however, claim 8 specifies the vector contains an amplifiable marker, which can be interpreted as a selectable marker. It would be obvious for one of ordinary skill in the art to add a selectable marker in the claimed vector and the selectable marker is under the control of another promoter

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because it is general practice to use a selectable marker to identify a transfected cell from non-transfected cell.

3. Claims 2-11 and 22 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 10 of U.S. Patent No. 6,740,503 ('503). Although the conflicting claims are not identical, they are not patentably distinct from each other because although drawn to different scope, they encompass the same invention and obvious variants thereof and are repeated for the reasons set forth in the preceding Official action mailed 1-29-08. Applicant's arguments filed 11-5-08 have been fully considered but they are not persuasive.

Applicants argue that the patents and application are either divisionals or continuations of divisionals from the original parent application 09/276,820, which has a restriction requirement. The '503 patent is directed to expressing a gene on genomic DNA and not by integrating the vector into a cellular genome (amendment, p. 12-13). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 1-29-08. Applicants just provide a general statement that the patents and applications are divisionals and continuations but fail to point out which patent or application corresponds to which group in the original restriction requirement of 09/276,820. It is unclear which group in the original restriction requirement of 09/276,820 corresponds to the claims of '503 patent. Although the vector of '503 patent comprises the genomic DNA fragment, however, the host cell comprising said vector could have said genomic DNA fragment or said vector integrated into the cellular genome and it would be obvious to one of ordinary skill in the art.

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4. Claims 2-11, 22, 26 and 27 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 11, 13, 19 and 20 of U.S. Patent No. 6,623,958 ('958, IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because although drawn to different scope, they encompass the same invention and obvious variants thereof and are repeated for the reasons set forth in the preceding Official action mailed 1-29-08. Applicant's arguments filed 11-5-08 have been fully considered but they are not persuasive.

Applicants argue that the patents and application are either divisionals or continuations of divisionals from the original parent application 09/276,820, which has a restriction requirement. The '958 patent is directed to using positive and negative selectable markers (amendment, p. 12-13). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 1-29-08. Applicants just provide a general statement that the patents and applications are divisionals and continuations but fail to point out which patent or application corresponds to which group in the original restriction requirement of 09/276,820. It is unclear which group in the original restriction requirement of 09/276,820 corresponds to the claims of '958 patent. Further, positive and negative selectable markers are selectable markers and would be obvious to one of ordinary skill in the art.

5. Claims 2-11, 22, 26 and 27 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 7, 8, 10-13, 16, 18, 19 and 21-28 of U.S. Patent No. 6,602,686 ('686, IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because although drawn to different scope, they

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encompass the same invention and obvious variants thereof and are repeated for the reasons set forth in the preceding Official action mailed 1-29-08. Applicant's arguments filed 11-5-08 have been fully considered but they are not persuasive.

Applicants argue that the patents and application are either divisionals or continuations of divisionals from the original parent application 09/276,820, which has a restriction requirement. The '686 patent is directed to a vector with two promoters, two exons, and two splice donors, but not directed to the specific design of the vector of instant invention (amendment, p. 12-13). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 1-29-08. Applicants just provide a general statement that the patents and applications are divisionals and continuations but fail to point out which patent or application corresponds to which group in the original restriction requirement of 09/276,820. It is unclear which group in the original restriction requirement of 09/276,820 corresponds to the claims of '686 patent. The exon of the vector in '686 could be a selectable marker lacking a polyadenylation signal. Further, although '686 patent does not specifically mention a selectable marker, however, claim 16 specifies the vector contains one or more amplifiable markers, which can be interpreted as a selectable marker. It would be obvious for one of ordinary skill in the art to add a selectable marker in the claimed vector and the selectable marker is under the control of a promoter because it is general practice to use a selectable marker to identify a transfected cell from non-transfected cell. The term "comprising" in the claims of the instant invention is an open language, although the '686 patent teaches two exons and two splice donors, the instant invention could contain more than one exon and more than one splice donor in the vector. Thus, they are obvious variants in view of the teachings of '686.

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6. Claims 2-11 and 22 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 92-99 and 110-116 of copending Application No. 10/331,329 ('329, IDS). Although the conflicting claims are not identical, they are not patentably distinct from each other because although drawn to different scope, they encompass the same invention and obvious variants thereof and are repeated for the reasons set forth in the preceding Official action mailed 1-29-08. Applicant's arguments filed 11-5-08 have been fully considered but they are not persuasive.

Applicants argue that the patents and application are either divisionals or continuations of divisionals from the original parent application 09/276,820, which has a restriction requirement. The '329 application is directed to vectors that do not necessarily contain two promoters (amendment, p. 12-13). This is not found persuasive because of the reasons set forth in the preceding Official action mailed 1-29-08. Applicants just provide a general statement that the patents and applications are divisionals and continuations but fail to point out which patent or application corresponds to which group in the original restriction requirement of 09/276,820. It is unclear which group in the original restriction requirement of 09/276,820 corresponds to the claims of '329 application. Further, although '329 does not specifically mention a selectable marker, however, the vector of '329 contains one or more sequence encoding an amplifiable marker, which can be interpreted as a selectable marker. It would be obvious for one of ordinary skill in the art to add a selectable marker in the claimed vector and the selectable marker is under the control of another promoter because it is general practice to use a selectable marker to identify a transfected cell from non-transfected cell.



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7. Applicant is advised that should claim 2 be found allowable, claim 3 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

### ***Conclusion***

No claim is allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.  
/Shin-Lin Chen/

Primary Examiner, Art Unit 1632